Claims 28-32 have also been rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to "recite a final process step which agrees back with the preamble". Applicants believe this rejection is not an issue in the new claims and therefore the issue is moot.

Claims 28-33 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,228,578. Applicants include herewith an executed terminal disclaimer. Reconsideration and withdrawal of this rejection is respectfully requested.

Claims 28 and 33 have been rejected under 35 U.S.C. §102(b) as being anticipated by Dattagupta. Applicants respectfully disagree with this rejection.

Dattagupta does not describe a kit as claimed. The test kit described in the Dattagupta reference does not contain all of the components of the claimed kits. In particular, Dattagupta does not describe a sample transport medium for stabilization of the sample. Also, Dattagupta does not teach or suggest a solid phase to which an anti-hybrid antibody is immobilized. The anti-hybrid antibody described in Dattagupta (col. 8, lns 54-60) does not relate to an immobilized antibody to capture the hybrid, but rather for detection. The antibody described in Dattagupta in col. 18, lns 19-23, does not relate to an anti-hybrid antibody, but rather an anti-*hapten* antibody, such as one directed to biotin. *See also* col. 3, ln. 64 – col. 5, ln. 5. Immobilization of the hybrid to a solid matrix is always carried out using a modified probe, i.e. one containing a hapten for binding purposes. As a result, the Dattagupta reference also does not teach or suggest the use of an unmodified probe in its test kit. Therefore, Dattagupta does not describe the components of the kit claims.

Also, the Dattagupta reference does teach or suggest a test kit which has an accuracy of at least 89%. The claims specifically require an accuracy level which must be

achieved. The Dattagupta reference does not teach or suggest how the skilled artisan could attain this level of accuracy in a test kit. Further, the Dattagupta reference does not teach or suggest test kits for detection of viral infections or *Chlamydial* infections.

For these reasons, applicants respectfully request reconsideration and withdrawal of this §102(b) rejection.

Claim 28 has been rejected under 35 U.S.C. §102(b) as being anticipated by Rashtchian. Applicants respectfully disagree with this rejection. Further, in view of cancellation of claim 28, the rejection is rendered moot.

Claim 33 has been rejected under 35 U.S.C.§103(a) as being unpatentable over Rashtchian. Applicants respectfully disagree with this rejection.

Rashtchian does not teach or suggest all of the elements of claim 33, nor is there any motivation in the Rashtchian reference to modify the assay to reach the claimed kit. In particular, Rashtchian describe the use of a biotinylated probe and a streptavidin conjugated peroxidase to detect the complex. The reference provides no teaching or suggestion on how the assay could be carried out with an unmodified probe, nor does the reference provide any motivation to change the format of the assay. Also, Rashtchian does not teach or suggest the use of a sample transport medium for stabilization of the sample, because Rashtchian's assay has no need for such a medium. One skilled in the art would not be motivated to construct a kit meeting the limitations of the instant claims based upon Rashtchian, because the assay is directed to a specific set of steps utilizing a specific set of reagents to detect a particular target nucleic acid. There is no teaching or suggestion in the Rashtchian reference to modify the probe to either be unmodified or to be directed to a different target nucleic acid. Therefore, applicants respectfully request reconsideration and withdrawal of this §103 rejection.

Claims 28-33 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Dattagupta in view of Thompson. Applicants respectfully disagree with this rejection.

As discussed above, Dattagupta describes a method which is different from the claimed kit in many respects. First, Dattagupta does not teach or suggest a method wherein an anti-hybrid antibody is used to immobilize a DNA/RNA hybrid. Rather, Dattagupta uses a probe modified to contain a hapten, which is then immobilized to a solid phase through non-covalent binding to its binding partner. *See* Dattagupta, col. 3, ln. 64 – col. 5, ln. 5, as discussed above. As a result, the probe used in the Dattagupta reference is modified, to be recognized by its binding partner. Thompson does not remedy the defects of the Dattagupta reference. It does not teach or suggest the use of an unmodified probe in a kit for the detection of a target nucleic acid using an anti-hybrid antibody to capture the hybrid to a solid surface. Therefore, Dattagupta in view of Thompson does not teach or suggest the kit as claimed. One skilled in the art would not be motivated to make the necessary changes to the kit or assay to reach the present claims. It is also noted that neither Dattagupta nor Thompson teach or suggest detection of specific target nucleic acid sequences as recited in the newly added claims. For these reasons, applicants respectfully request reconsideration and withdrawal of this §103 rejection.

Claims 28-32 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Rashtchian in view of Thompson. Applicants respectfully disagree with this rejection. However, in view of cancellation of claims 28-32, the rejection is rendered moot.

Allowance of the pending claims is respectfully requested. Early and favorable action by the Examiner is earnestly solicited.

AUTHORIZATION

No additional fee is believed to be necessary.

The Commissioner is hereby authorized to charge any additional fees which may be required for this amendment, or credit any overpayment to Deposit Account No. 13-4500, Order No. 2629-4023.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 13-4500, Order No. 2629-4023. A DUPLICATE OF THIS SHEET IS ATTACHED.

Respectfully submitted,

MORGAN & FINNEGAN, L.L.P.

Dated: March 13, 2002

By: _____
Dorothy R. Auth
Reg. No. 36,434

MORGAN & FINNEGAN, L.L.P.
345 Park Avenue
New York, N.Y. 10154
(212) 758-4800
Fax (212) 751-6849

VERSION WITH MARKINGS SHOWING CHANGES

33. (amended) A solution hybridization kit for the detection of a target nucleic acid sequence for diagnosing genetic defects, microbial or viral infections in a biological sample with an accuracy of at least 89% comprising:

a) a sample transport medium for stabilization of the biological sample;

b) an unmodified probe complementary to the target nucleic acid sequence for formation of a double-stranded RNA/DNA hybrid;

c) a solid phase to which an anti-hybrid antibody or a functional anti-hybrid antibody fragment has been immobilized, wherein the antibody or antibody fragment specifically binds to a component of the double-stranded RNA/DNA hybrid; and

d) means for detecting the hybrid formed by hybridization of the probe and the target nucleic acid sequence.